

REMARKS

Entry of the foregoing, reexamination and reconsideration of the above-identified application, pursuant to and consistent with 37 C.F.R. §§ 1.116 and 1.176(a), are respectfully requested.

Status

As is correctly reflected in the Final Office Action Summary, Claims 16-26, 28-38, 64, and 65 were pending in this reissue application. Claims 16-26, 28-38, 64, and 65 stand rejected. The Specification is objected to by the Examiner and the drawings filed on June 27, 2004, have been accepted.

Personal Interview

Applicants and their undersigned representatives thank Examiner Russel for the courtesies extended during the personal interview conducted on November 2, 2006 between Examiner Russel and Ms. Erin M. Dunston (Registration No. 51, 147). As is correctly reflected in the Interview Summary, it was verified during the Interview that Applicants' submission filed October 3, 2006, was *not* intended as a response to the final rejection issued August 29, 2006. It was also discussed at the Interview that the executed Substitute Reissue Declarations filed on October 3, 2006, satisfy the requirements for a claim for priority under 35 U.S.C. § 119(a)-(d) and for a reissue declaration with a statement regarding no deceptive intent. Should additional substantive amendments be filed, additional Reissue Declarations would be necessary. Also discussed during the Interview was the meaning of the term "predominantly" as it pertains to the claim phrase "wherein said CNS injury predominantly affects glia." Finally discussed during the

Interview was the concept that Examiner Russell would appreciate additional information regarding interference estoppel.

Summary Of Amendments To The Title, Specification, and Claims

According to the Final Office Action mailed August 29, 2006, the amendments to the title, Specification, and claims made on August 4, 2006, are not in compliance with 37 C.F.R. §§ 1.173(b) and (d). *Final Office Action, Page 2, ¶ 1*. By the instant amendments, Applicants have repeated the amendments made on August 4, 2006 to the Title and Specification, but have satisfied all requirements of 37 C.F.R. §§ 1.173(b) and (d). Accordingly, Applicants respectfully request entry of these amendments.

Further by the foregoing amendments, Applicants have canceled Claims 17-26 and 29-38 without prejudice or disclaimer to Applicants filing one or more continuation applications directed to the previously-presented subject matter contained therein.

Further by the foregoing amendments, Applicants have added new Claims 66-77. Claims 66-71 depend from Claim 16 but specify that said CNS injury is a demyelinating disorder (Claim 66), multiple sclerosis (Claim 67), periventricular leucomalacia (Claim 68), carbon monoxide inhalation (Claim 69), ammonia intoxication (Claim 70), and gaseous intoxication (Claim 71). Support for Claims 66-71 may be found throughout the Specification, and at least at: for Claim 66, at original Claim 9; for Claim 67, at Column 1, Lines 45-46 and original Claim 8; for Claim 68, at Column 1, Lines 24-29; for Claim 69, at Column 1, Lines 48-56; for Claim 70, at Column 1, Lines 48-56; and for Claim 71, at Column 1, Lines 48-56. Accordingly, no new matter has been added.

Claims 72-77 depend from Claim 28 but specify that said CNS injury is a demyelinating disorder (Claim 72), multiple sclerosis (Claim 73), periventricular leucomalacia (Claim 74), carbon monoxide inhalation (Claim 75), ammonia intoxication (Claim 76), and gaseous intoxication (Claim 77). Support for Claims 72-77 may be found throughout the Specification, and at least at: for Claim 72, at original Claim 9; for Claim 73, at Column 1, Lines 45-46 and original Claim 8; for Claim 74, at Column 1, Lines 24-29; for Claim 75, at Column 1, Lines 48-56; for Claim 76, at Column 1, Lines 48-56; and for Claim 77, at Column 1, Lines 48-56. Accordingly, no new matter has been added.

Ownership Of The Instant Reissue Application

The Examiner has requested papers sufficient to establish the consent of the assignee for the reissue application. *Final Office Action, Pages 2-3, ¶ 3.* Applicants respectfully submit that the papers previously filed in this reissue application were sufficient and not contradictory. However, since that filing there has been a change of ownership. Specifically, Genentech, Inc. is now the owner of all right, title, and interest to this reissue application. Once the Reel and Frame Numbers for the recordation of Genentech's sole ownership of the instant reissue application are available, Applicants will submit Form PTO/SB/53 (Reissue Application: Consent of Assignee) and Form PTO/SB/96 (Statement Under 37 C.F.R. § 3.73(b)).

Applicants believe the proposed paperwork will satisfy the Examiner's request for papers sufficient to establish the consent of the assignee for the reissue application.

Status Regarding U.S. Patent No. 5,583,114

The Examiner reminded Applicants of their continuing obligation to alert the Office of any prior or concurrent proceeding regarding U.S. Patent No. 5,583,114. *Final Office Action, Page 3, ¶ 4*. Applicants respectfully submit that this passage may have been written in error. U.S. Patent No. 5,583,114 is directed to an “Adhesive Sealant Composition,” which issued on December 10, 1996. Applicants respectfully request that the Examiner clarify this reminder.

Claim For Priority

The Examiner indicated that “there is no claim for priority under 35 U.S.C. 119(a)-(d) present in this reissue application.” *Final Office Action, Page 3, ¶ 5* (citing M.P.E.P. § 1417). M.P.E.P. § 1417 states that “[a] ‘claim’ for the benefit of an earlier filing date in a foreign country under 35 U.S.C. 119(a)-(d) must be made in a reissue application, even though such a claim was previously made in the application for the original patent to be reissued. However, no additional certified copy of the foreign application is necessary. . . . In addition, 37 CFR 1.63 requires that in *any* application in which a claim for foreign priority is made pursuant to 37 CFR 1.55, the oath or declaration must identify the foreign application for patent”

In addition to reiterating in the instant amendment Applicants’ claim for priority under, *inter alia*, 35 U.S.C. § 119(a)-(d), Applicants submitted, on October 3, 2006, Substitute Reissue Declarations that stated “Applicants claim priority of New Zealand Application 239211 filed on August 1, 1991.” Applicants believe the instant reissue application now fully complies with all requirements for claiming priority, including M.P.E.P. § 1417, as was verified during the Interview.

Accordingly, Applicants believe the instant reissue application should receive the benefit of the filing date of New Zealand Application 239211, *i.e.*, August 1, 1991.

Reissue Oath/Declaration

The Examiner indicated that the “reissue oath/declaration filed with the application is defective because it fails to contain a statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant.” *Final Office Action, Page 4, ¶ 6* (citing 37 C.F.R. § 1.175 and M.P.E.P. § 1414).

On October 3, 2006, Applicants submitted Substitute Reissue Declarations that stated “[w]e agree that all errors which are being corrected in the reissue application up to the time of filing the oath/declaration arose without any deceptive intention on the part of the Applicants.” Applicants believe the instant reissue application now fully complies with all requirements for a proper reissue application, including 37 C.F.R. § 1.175 and M.P.E.P. § 1414, as was verified during the Interview.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 16-26, 28-38, 64, and 65 as being based on a defective reissue declaration under 35 U.S.C. § 251 as it applies to Claims 16, 28, and 64-77. *See Final Office Action, Page 4, ¶ 6.*

Objection To The Disclosure

The Examiner objected to the disclosure because the amended claim for priority in the paragraph beginning at Column 1, Line 3 of the Specification contained an incorrect issue date for U.S. Patent No. 5,714,460. *Final Office Action, Page 4, ¶ 7.*

By the instant amendments, Applicants have corrected the disclosure to correctly reflect that U.S. Patent No. 5,714,460 issued on February 3, 1998. Accordingly, Applicants respectfully request withdrawal of this objection to the disclosure.

Rejections Based On Purported New Matter

Claims 16-26, 28-38, 64, and 65 and the amendment filed on August 4, 2006 were rejected under 35 U.S.C. §§ 132(a) and 251 as being based upon new matter added to the patent for which reissue is sought. *Final Office Action, Pages 4-5, ¶¶ 8, 9*. These rejections were based on the incorporation by reference to New Zealand Patent Application 239211. *See id.* These rejections are respectfully traversed.

Not to acquiesce in the Examiner's rejections, but solely to facilitate prosecution, Applicants have amended the Specification so as to incorporate by reference only U.S. Patent Application Serial No. 08/185,804 and International Patent Application PCT/US92/06389. Such incorporations are expressly set forth in U.S. Patent No. 5,714,460 at Column 1, Lines 3-8. Accordingly, Applicants believe no new matter has been added and Applicants respectfully request withdrawal of the rejection of Claims 16-26, 28-38, 64, and 65 under 35 U.S.C. §§ 132(a) and 251 as it applies to Claims 16, 28, and 64-77.

Indication of Allowable Subject Matter

Applicants note with appreciation the Examiner's statement that the content of what are now Claims 64 and 65 (which were Claims 46 and 58) is "novel and unobvious over the prior art of record or any combination thereof." *See Office Action mailed April 4, 2006, Page 11, ¶ 16.*

Rejection Under 35 U.S.C. § 112, Second Paragraph – Indefiniteness

Claims 16-25 and 28-37 were rejected under 35 U.S.C. § 112, Second Paragraph, as purportedly indefinite due to the phrase “wherein said CNS injury predominantly affects glia.” *Final Office Action, Pages 5-6, ¶ 10*. This rejection is respectfully traversed, including as it applies to Claims 16, 28, and 66-77.

When deciding whether claims comply with 35 U.S.C. § 112, Second Paragraph, one does not analyze the claim language in a vacuum, but instead in light of the content of the application, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the art at the time the invention was made. *See M.P.E.P. § 2173.02*. Applicants respectfully submit that the meaning of Claims 16, 28, and 66-77 is readily ascertainable. Applicants furnish herewith the Declaration of Azad Bonni, M.D., Ph.D. (“Bonni Declaration”) to further clarify the meaning of Claims 16, 28, and 66-77 as would one of skill in the art.

Independent Claims 16 and 28 specify that the “CNS injury predominantly affects glia.” The central nervous system, or “CNS,” includes the brain and spinal cord and their respective components. *See Bonni Declaration, ¶ 9*. Glia are non-neuronal cells that provide support and nutrition, maintain homeostasis, form myelin, and participate in signal transmission in the central nervous system. *See Bonni Declaration, ¶ 10*. Glia also form and maintain the blood-brain barrier and regulate the activity of neurons. *See Bonni Declaration, ¶ 10*. Glia also play a key role in brain development. *See Bonni Declaration, ¶ 10*.

A CNS injury that predominantly affects glia is one that results in abnormalities primarily to the resident glial cells, including astrocytes, oligodendrocytes, and ependymal cells. *See Bonni Declaration, ¶ 11*. There are known pathogenic insults that predominantly affect glia,

including demyelinating diseases, multiple sclerosis, periventricular leucomalacia, carbon monoxide inhalation, ammonia intoxication, and gaseous intoxication. *See Bonni Declaration*, ¶¶ 12-18. These insults predominantly affect glia, in particular, oligodendrocytes, and do not predominantly affect neurons. *See Bonni Declaration*, ¶¶ 11-18.

In view of the foregoing, Applicants respectfully submit that the meaning of Claims 16, 28, and 66-77 is readily appreciated by those of skill in the art and respectfully request withdrawal of the 35 U.S.C. § 112, Second Paragraph, indefiniteness rejection.

Rejections Under 35 U.S.C. § 103 – Interference Estoppel

Claims 16-18, 23-26, 28-30, and 35-38 were rejected under 35 U.S.C. § 103 as purportedly estopped on the merits by final judgment in Interference No. 104,533. *Final Office Action*, Pages 6-8, ¶ 12. According to the Examiner, “[i]t would have been obvious to one of ordinary skill in the art at the time Applicants’ invention was made to treat glial cells damaged by CNS injury which predominantly affects glia, because the interference count specifically recites that injured glia cells are to be treated, and the lack of injury to other types of cells would not have been expected to interfere with the ability of IGF-1 and its analogues to treat injured glia cells.” *Final Office Action*, Pages 6-7, ¶ 12. Claims 16, 24-26, 28, and 36-38 were also rejected under 35 U.S.C. § 102(g) and/or § 103 as being estopped on the merits by final judgment in Interference No. 104,533. *Final Office Action*, Pages 8-9, ¶ 13. These rejections are respectfully traversed, including as it applies to Claims 16, 28, and 66-77.

During the course of Interference 104,533, the Count was Gluckman Claim 1 from the ‘460 patent OR Gluckman Claim 1 of U.S. Patent No. 5,861,373 OR Lewis Claim 129 from U.S. Patent Application Serial No. 09/064,159 OR Lewis Claim 135 of U.S. Patent Application Serial

No. 09/318,001. *Decision on Motion in Interference 104,533, Paper No. 111, ¶¶ 1-5, 12, 13.*

During Interference 104,533, the Count was given its broadest reasonable construction. *Decision on Motion in Interference 104,533, Paper No. 111, Page 40.* The Board noted that the “broadest reasonable construction of Gluckman’s 460 claim 1 and 373 claim 1 is that the treatment must be for a CNS insult ‘affecting’ glia or other non-cholinergic cells, but may also affect cholinergic neurons.” *Id.*

In contrast, Applicants Claims 16, 28, and 66-77 are directed to the treatment of CNS injury wherein the CNS injury *predominantly affects glia*. As noted in the Decision on Motions in Interference 104,533, “neither party discloses a targeted treatment in a patient of one type of CNS cell to the exclusion of other CNS cells.” *Decision on Motion in Interference 104,533, Paper No. 111, ¶ 26.* Applicants respectfully submit that the Count from Interference 104,533 does not anticipate nor render obvious Applicants claims which now specifically require that the CNS injury predominantly affects glia. A claim is anticipated only if each and every element as set forth in the claim is found in the cited publication. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The Count from Interference 104,533 does not disclose each and every element of Applicants’ Claims 16, 28, and 66-77. Similarly, to establish a *prima facie* case of obviousness, (1) there must be some suggestion or motivation to modify the reference or combine teachings, (2) there must be a reasonable expectation of success, and (3) the prior art must teach or suggest all of the claim limitations. *See M.P.E.P. § 2142.* A *prima facie* case of obviousness cannot be made against Applicants’ Claims 16, 28, and 66-79 because the Count from Interference 104,533 does not disclose each and every element of those claims. For example, the Count from Interference 104,533 does not specifically require that the CNS injury predominantly affects glia.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection of Claims 16, 28, and 66-77 due to interference estoppel.

Moreover, a party cannot seek to add a claim to an application in interference and request that it be designated as not corresponding to the Count. *L'Esperance v. Nishimoto*, 18 U.S.P.Q.2d 1534 (Bd. Pat. App. & Int. 1991). The Decision on Motions from Interference 104,533 notes that because Gluckman could *not* add narrower claims, such as Claims 16, 28, and 66-77, Gluckman would *not be estopped* from filing a reissue application seeking narrower claims that would not have been obvious in view of the subject matter of the lost count to the extent Gluckman's specification supports such claims. *Decision on Motion in Interference 104,533, Paper No. 111, Page 23, Page 23, n.17*. Above, Applicants have set forth why Claims 16, 28, and 66-77 are neither anticipated nor rendered obvious by the Count and have set forth where the '460 Specification supports Claims 16, 28, and 66-77.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 16, 28, and 66-77 due to interference estoppel.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this Amendment and Reply or to the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (202) 373-6000 so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2518.

Respectfully submitted,
BINGHAM MCCUTCHEN, LLP

Date: February 28, 2007

By:

A handwritten signature in black ink, appearing to read "Erin M. Dunston", written over a horizontal line.

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